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Regarding the follo	wing Application:		
Applicant(S):	STEINER, Mitchell S. et al.	Examiner:	Fubara, Blessing M
Scrial No./ Patent No.:	10/747,686	Group Art Unit:	1618
Filed/Issued Date:	December 30, 2003	Attorney Docket No.:	P-2769-US9
Title:	A METHOD FOR CHEM	MOPREVENTION C	OF PROSTATE CANCER
☐ Transmittal Sheet Containing: Pages of Si Pages of C Page of Ab Pages of ☐ Pages of ☐ Pages of ☐ Control Co	ication Transmittal Sheet Leet Under 35 USC 111(a) Application Under 35 USC 111(b for Entering National Phase Decification Laims Stract Formal Drawings A Power of Attorney Lion of Recordation of Assign. and	10. Response to No 11. Request for Co 12. Information Di - Form P1O/Si) 13. Preliminary An 14. Response to Of dated 15. Petition for a O 16. Notice of Apper 17. Submission of I Submission of I Copy of Priorit 20. Claim for Coav 11. Revocation and - Statement Ua - Copy of Assig	The Action In Month(s) Extension of Time al

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Attorney Docket No.: P-2769-US9

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: STEIN

STEINER, Mitchell S. et al.

Examiner:

Fubara, Blessing M

Serial No.:

10/747.686

Group Art Unit:

1615

Filed:

December 30, 2003

Title:

A METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER

Mail Stop Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO-1449:

- 1. \(\subseteq \) listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents, and/or United States patent applications, and/or United States patent application publications are not included in this information disclosure statement; and/or
- 2. Issting documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Scrial No. 10/611,056, filed July 2, 2003 which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
- 3. I listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement 12/5/555
- 4. Isiting other information for the Examiner's consideration which 18 was Deited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement/33/2867 MBLANCO 03000012 10747686

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APPLICANTS:

STEINER, Mitchell S. et al.

SERIAL NO.:

10/747,686

FILED:

December 30, 2003

Page 2

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

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- II) After the period specified in (1) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;
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STEINER, Mitchell S. et al. 10/747,686

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ubmitted,

Mark S. Cohen

Attorney for Applicants Registration No. 42,425

Dated: August 1, 2007

PEARL COHEN ZEDEK LATZER LLP 1500 Broadway, 12th Floor New York, NY 10036

Phone: (646) 878-0800 Fax: (646) 878-0801

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	Substitute for form 1449A/PTO			Complete if Known		
		Application Number	10/747,688			
INF	ORMAT	TION	DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT		First Named Inventor	STEINER, Mitchell S.			
				Group Art Unit	1615	
(use as many sheets as necessary)		Examiner Name	Not yet known			
Sheet	1	of	9	Attorney Docket Number	P-2769-US9	

			U.	S. PATENT DOCUMENTS		
Examiner Initlals*	Cite, No.		d Code ² crown)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	Α	4,990,538	T	Harris et al.	February 5, 91	
	В	5,788,964		Baral et al.	August 4, 98	
	C	5,650,425		Biegnon et al.	July 22, 97	
	D	4,696,949		Toivola et al.	Sept 29, 87	
	E	5,491,173	1	Toivola et al.	Feb. 13, 1996	
	F	5,571,534		Jalonen et al.	Nov. 5, 1996	
	G	5,605,700		DeGregorio et al.	Feb. 25, 1997	
	Н	5,595,722		Grainger et al.	Jan. 21, 1997	
	1	5,599,844		Grainger et al.	Feb. 4, 1997	
	J	5,629,007		Audia et al.	May 13, 1997	
	K	5,635,197		Au <u>dia et al.</u>	June 3, 1997	
	L	5,595,985	<u> </u>	Labrie	Jan. 21, 1997	
	M	5,441,986		Thompson, et al	08-15-1995	
	N	5,852,059		Thompson, et al	12-22-1998	
	0	5,827,892		Loeser, et al	10-27-1998	
	Р	5,821,254		Sporn, et al	10-13-1998	
	Q	5,859,045		Treppendahl, et al	01-12-1999	
	R	5,935,987		Treppendahl, et al	08-10-1999	
	S	2005/0171073		Steiner, et al	01-2006	

			FORI	IGN PATENT DOCUME	ENT8		
Examiner Initials*	Cite No.		gnPatent Document Kind Code ^s Number (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	76
_	Т	wo	98/58634		December 30, 98		
	U	EP	415 623 A2	Harris et al	March 6, 1991		
	v	EP	616 529 B1		September 28, 94		
	W	EPC	095875		Dec 7, 1995		
	х	ΜΦ	95/26720	Biegon et al	Oct 12, 1995		
	Υ	wo	0008001		Feb 17, 2000		

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Signature		Considered	

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INFORMATION DISC	LOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT		First Named Inventor	STEINER, Mitchell S.	
		Group Art Unit	1615	
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Sheet 2 of 9		Attorney Docket Number	P-2769-US9	

		U.	S. PATENT DOCUMENTS		
Examiner Initiøls*	Cite, No.	U.S. Patent Document Number Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	z	4,329,364	Neri et al.	May 11, 1982	
	AA	4,474.813	Neri et al.	Oct. 2, 1984	
	АВ	6,080,877	Swindell et al	June, 2000	
	AC	6,265,448	Steiner et al	July 24, 2001	
	AD	6,410,043	Steiner et al	June 25, 2002	
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	АН	6,413,535	Steiner et al	July 2, 2002	
	Al	4,996,225	Toivola et al	Feb 26, 1991	
	AJ	5,811,120	Gibson et al	Sept 22, 1998	
	AK	5,972,383	Gibson et al	Oct 26, 1999	
	AL	4,418,068	Jones	Nov 29, 1983	

			FORE	IGN PATENT DOCUM	ENTS		•
		Forei	gnPatent Document	Name of Patentee or	Date of Publication of	Pages, Columns, Lines,	
Examiner Initials*	Cite, No.	Office ³	Number Kind Codes (if known)	Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	T€
	AM	wo	94/12162	Warri et al	June 9, 1994		
	AN	wo	99/56739	Steiner et al	November 11, 1999		
	AO	wo	00/47214	Healey et al	August 17, 2000		
	AP	wo	96/09046	Audia et al	March 28, 1996	"	
	AQ	EP	0 670 162	Gibson et al	Sept 6, 1995		
	AR	wo	00/19998	KGK Synergize	04-13-2000		
	AS	wo	97/25038	Novo Nordisk	7-17-1997		
	AT	wo	99/08682	Duke University	02-25-1999		
	ΑÜ	wo	97/25037	Novo Nordisk	7-17-1997		

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			Application Number	10/747,686	
INFORMATION DISCLOSURE			DISCLOSURE	Filing Date	December 30, 2003
STATEMENT BY APPLICANT		BY APPLICANT	First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1615
(use as many sheets as necessary)		Examiner Name	Not yet known		
Sheet	3	of	9	Attorney Docket Number	P-2769-US9

		NON PATENT LITERATURE DOCUMENTS	
Examiner nitials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	ΑV	Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", in J. Cancer Education, 1993, Vol. 8, No. 2, pages 91-107.	
	AW	Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5.	
	AX	Kelloff et al., "Introductory Remarks: Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 1611: 1-8.	
	AY	Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxyphenyl)retinamide, and the Vitamin 1) Analogue Ro24-553 I for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627.	
	AZ	Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Following Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442.	
	BA	Schneider Martin R. et al. "Nonsteroidal Antlestrogens and l'artial histrogens with Prostatic Tumor Inhibiting Activity", Cancer Research Clinical Oncology Springer-Verlag 1986, J Cancer Res Clin Oncol (1986) 112: 258-265, p. 258-265,	
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	ВС	Valavaara Ritva, MD, PhD "Reliability of Estrogen Receptors in Predicting Response To Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18.	
	BD	Richard Gams, MD "Phase III Trials of Toremifene vs Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997	
	BE	Christian Rohlff et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen Is Associated With Inhibition of Protein Linase C and Induction of p21" The Prostate 37:51-59 (1998) ©1998 Wiley-Liss, Inc	
	BF	Nevalanine et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Ress, vol. 53, no. 21, 1993, pages 5199-5207, XO0021 17653.	
	BG	Gingrich et al., "Androgen-independent Prostate Cancer Progression in the TRAMP Model", in Cancer Research 57, November 1, 1997, pages 4687-4691.	
· · · · · · · · · · · · · · · · · · ·	ВН	Gingrich et al., "Pathalogic Progression of Autochthonous Prostate Cancer in the TRAMP Model", Prostate Cancer and Prostatic Diseases, 1999, 2, Pages 70-75.	
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	ВЈ	Gershanovich et al., " A Phase III Comparison of Two Toremifene Doses to Tamoxifen in Postmenopausal Women with Advanced Breast Cancer", Breast Cancer Research and Treatment 45, 1997, Pages 251-262.	

Examiner	Date	
Signature	Considered	

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	Substitu	ite for fo	нт 1449В/РТО	Complete if Known		
				Application Number	10/747,686	
INFORMATION DISCLOSURE				Filing Date	December 30, 2003	
STATEMENT BY APPLICANT			BY APPLICANT	First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1615	
(use as many sheets as necessary)			eets as necessary)	Examiner Name	Not yet known	
Sheet	4	of	9	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	вк	Hayes et al. "Randomized Comparison of Tamoxifen and Two Separate Doses of	1
		Toremifenein Postmenopausal Patients with Metastatic Breast Cancer", Journal of Clinical	
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-	ВМ	Neubauer et al., "Endocrine and Antiprostatic Effects of Raloxifene (LY156758) in the Male	-
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		Molecular and Cellular Endocrinology 39, 1985, pages 141-144.	
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		Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast	
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	 	(LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458	
	BS	Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by	1
		177-Estudiol", in J. Clin. Invest. © The American Society for Clinical Investigation, Inc.,	1
		Vol. 63 March 1979, pages 351-357.	
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	BU	Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Int. J Cancer: 57, 224-228 (1994) Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106.	+
	BV	Shenfeld et al. "Androgen Deprivation Therapy", Chapter 37, Section III/Prostate Cancer,	-
	5	pages 467-477	
	BW	Jordan VC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2) 271	-
		Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Anticstrogen	
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		1998 Mar; 12(3 Suppl 5): 28-31.	
	BZ	Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone	
		Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and	
		Progesterone", Anticancer Res 1994 May-June; 14(3A): 889-93.	

Examiner	Date	
Signature	Considered	

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Substitute for form 1449B/PTO				Complete if Known		
				Application Number	10/747,686	
INFORMATION DISCLOSURE				Filing Date	December 30, 2003	
STATEMENT BY APPLICANT		First Named Inventor	STEINER, Mitchell S.			
				Group Art Unit	1615	
(use as many sheets as necessary)			ets as necessary)	Examiner Name	Not yet known	
Sheet 5 of 9		Attorney Docket Number	P-2769-US9			

		NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	No.1 publisher, city and/or country where published.					
	CA	Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors in Rat Dorsal and Lateral Prostate", Endocrinology 1996 Jul; 137(7): 3078-88.				
	СВ	Foekens JA et al. "Expression Of Prostate-Specific Antigen (PSA) Correlates With Poor Response To Tamoxifen Therapy In Recurrent Breast Cancer", Br J Cancer 1999 Feb; 79(5-6): 888-94.				
	СС	Brandes 1.1 et al. "Salutary Clinical Response Of Prostate Cancer To Antiandrogen Withdrawal: Assessment Of Flutamide In An In Vitro Paragdigm Predictive Of Tumor Growth Enhancement", Clin Cancer Res 1997 Aug; 3(8): 1357-61.				
	CD	Miyata E et al. "Effects Of Tamoxifen, An Anticstrogen, On Rat Prostate Carcinogenesis by 3,2'-Dimethyl-4-Aminohiphenyl And Testerone Do Not Support An Estrogen Role In Testerone Promotion", Prostate 1997 Apr 1;31(1)9-13.				
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	CF	Pienta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", Prostate1995 May; 26(5): 270-4.				
	CG	Lippman SM et al. "Cancer Chemoprevention", J Clin Oncol 1994 Apr; 12(4):851-73.				
	СН	Szarka CE et al. "Chemoprevention Of Cancer", Curr Probl Cancer 1994 Jan-Feb; 18(1):6-79.				
	CI	Bergan RC et al. "A Phase II Study Of High-Dose Tamoxifen In Patients With Hormone-Refractory Prostate Cancer." Clin Cancer Res 1999 Sep; 5(9): 2366-73.				
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	CK	Shughrue Paul J. et al. "Comparative Distribution Of Estrogen Receptor-? (Er-?) And? (Er-?) mRNA In The Rat Pituitary, Gonad, And Reproductive Tract." Steroids 63: 498-504, 1998, Elsevier Science Inc.				
	CL	Prins Gail S. et al, "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression in The Developing And Adult Rat Prostate Lobes*", Endocrinology 138: 1801- 1809, 1997)				
	СМ	Hempstock J. et al. "Growth Inhibition Of Prostate Cell Lines In Vitro By Phyto- Oestrogens", British Journal Of Urology (1998). 82. 560-563.				
	CN	Awoniyi Caleb A. et al. "Neonatal Exposure To Councestrol, A Phystocstrogen, Does Not Alter Spermatogenic Potential In Rats", Endocrine, vol. 7, no. 3, 337-341, December 1997.				
*** *	co	"Chemoprevention Of Prostate Cancer: Guidelines For Possible Intervention Strategies", Journal of Cellular Biochemistry, Supplement 16H:140-145 (1992).				

Examiner	 Date	
Signature	 Considered	

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PTO/SB/08A (10-98)

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Substitute for form 1449B/PTO	Complete if Known			
	Application Number	10/747,686		
INFORMATION DISCLOSURE	Filing Date	December 30, 2003		
STATEMENT BY APPLICANT	First Named Inventor	STEINER, Mitchell S.		
	Group Art Unit	1615		
(use as many sheets as necessary)	Examiner Name	Not yet known		
Sheet 6 of 9	Attorney Docket Number P-2769-US9			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials"	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	ť
	CP	"When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 1611:138-139 (1992).	
	CQ	"Editorial: A New Actor In The Estrogen Receptor Drama-Entre ER-?", Endocrinology Vol. 138, No. 3, (1997).	
	CR	Kulper George G. J. M. et al. "Comparison Of The Ligand Binding Specificity And Transcript Tissue Distribution Of Estrogen Receptors? and?", Endocrinology Vol. 138, No. 3, 863-870 (1997).	
		Colletta Anthony A. et al. "Alternative Mechanisms Of Action Of Anti-Ocstrogens" Breast Cancer Research and Treatment 31: 5-9, 1994.	
	CT	Griffiths K. et al. "Further Insights Into Endocrine Disease - Diet and Prostate Disease" An IPHC Teaching Programme.	
	ÇŲ	Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Taxoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3)291-300.	
	cv	Horton J et al. "Tamoxifen In Advanced Prostate Cancer: An ECOG Pilot Study", Prostate 1988; 12(2):173-7.	
	cw	Kangas L "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399.	
	ÇX	Anttila M et al. "Pharmacokinetics Of The Novel Antiestrogenic Agent Toremifene In Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 57(6):628-35.	
	CY	Kamat AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161. 1748-1760. June 1999, p. 1748-1760.	
	CZ	Fleton SA "Potential New Anticstrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52	
	DA	Nevalainen M.T. et al. "Estrogen and Prolactin Regulation of Rat Dorsal and Lateral Prostate in Organ Culture", Endocrinology, Vol. 129, No. 2 pages 612-618	
	DB	Moon R.C. et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifenc, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Research 14: 889-894 (1994)	
·	DC	Price K. R. et al. "Naturally Occurring Oestrogens in Food - A review", Food Additives and Contaminants, 1985, Vol. 2, No. 2, 73-106.	

Examiner	Date	
Signature	 Considered	

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PTO/SB/08A (10-96)

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Substitute for form 1449B/PTO				Complete if Known		
				Application Number	10/747,686	
INFORMATION DISCLOSURE			DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT		First Named Inventor	STEINER, Mitchell S.			
				Group Art Unit	1615	
(use as many sheets as necessary)		Examiner Name	Not yet known			
Sheet 7 of 9		9	Attorney Docket Number	P-2769-US9		

Examiner Initials*	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the	
	No.1	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	DD	Cheng E et al. "Endocrinology Of The Prostate", Prostate Diseases, chapter 5- p. 57-71.	
	DE	Bonkhoff II et al. "Estrogen Receptor Expression In Prostate Cancer and Premalignant Prosatic Lesions", American Journal of Pathology, Vol. 155, No. 2 August 1999.	
	DF	"New Research Approaches in The Prevention And Cure Of Prostate Cancer", American Association For Cancer Research, December 1998	
	DĞ	Xiaolin Zi et al. "Silibinin Decreases Prostate-Specific Antigen With Cell Growth Inhibition Via GI Arrest, Leading To Differentiation Of Prostate Carcinoma Cells: Implications For Prostate Cancer Interventions, Proc. Nsil. Acad. Sci. USA Vol. 96, pp. 7490-7495, June 1999. Medical Sciences.	l
	DH	Landstrom M, et al. "Inhibitory Effects Of Soy and Ryc Diets On The Development Of Dunning R3327 Prostate Adenocarcinoma in Rats, The Prostate 36: 151-161 (1998).	
	DI	Buelke-Sam J. et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology And Reproductive And Developmental Testing", Reprod Toxicol 1998 May-June; 12(3):217-21.	
	DJ	Treinen KA et al. "An Evaluation Of The Novel Selective Estrogen Receptor Modulator, Idoxifene, For Effects On Reproduction In Rats And Rabbits:, Toxicol Sci 1998 Feb; 41(2):199-207.	
	DK	Bochm S et al. "Estrogen Suppression As A Pharmacotherapeutic Strategy In The Medical Treatment Of Benign Prostatic Hyperplasia: Evidence For Its Efficacy From Studies With Mepartricin" Wien Klin Wochenschr 1998 Dec 11; 110(23):817-23.	
	DL	Dhar JD et al. "Estrogen, Androgen and Antiestrogen Responses in The Accessory Organs Of Male Rats During Different Phases Of Life", Endocr Res 1998 May; 24(2): 159-69.	
	DM	West Neal B et al. "Estrogen and Progestin Receptors And Aromatase Activity In Rhesus Monkey Prostate" Endocrinology, Vol. L. 123, (1998)	
	DN	Strauss L "Genistein Exerts Estrogen-Like Effects In Male Mouse Reproductive Tract", Molecular and Cellular Endocrinology 144 (1998) 83-93, Elsevier Science Ireland Ltd.	

Examiner	Date	
Signature	Considered	

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	Substit	ute for f	orm 1449B/PTÖ	Complete if Known		
				Application Number	10/747,686	
INF	ORMA	ATIO	N DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT			BY APPLICANT	First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1616	
(use as many sheets as necessary)			eets as necessary)	Examiner Name	Not yet known	
Sheet	8	of	9	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the Item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	DO	Hobisch Alfred "Metastatic Lesions From Prostate Cancer Do Not Express Oestrogen And Progesterone Receptors" J. Pathol. 182: 356-361, 1997.	
-	DP	Albert David S. et al. "An Overview Of Clinical Cancer Chemoprevention Studies With Emphasis On Positive Phase III Studies" Overivew of Diet Cancer 6928-6975 (1995)	
	DQ	Strom Sara S. et al. "Phytocstrogen Intake and Prostate Cancer; A Case-Control Study Using A New Database", Nutrition and Cancer, 33(1), 20-25. (1999).	
	DR	Kellof GJ et al "Strategies For Chemoprevention Of Prostate Cancer", Prostate Cancer and Prostate Disease (1988) 5, 107.	
, mee allend	DS	Buelke-Sam Judy et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology and Reproductive Development Testing", Reproductive Toxicology Vol. 12, No. 3 pp. 217-221, 1998.	
	DT	Prins Gail S. "Developmental Estrogenization Of The Prostate Gland", Prostate:Basic and Clinical Aspects p. 245-263 (1997).	
	DU	Kuiper George G. J. M. "Cloning Of A Novel Estrogen Receptor Expressed In Rat Prostate And Ovary", Proc. Natl. Acad. Sci USA Vol. 93, pp. 5925-5930, June 1996 Biochemistry.	
	DV	Kuiper George G. J. M. "Interaction Of Estrogenic Chemicals and Phytoestrogens With Estrogen Receptor?", Endocrinology Vol. 139, No. 10 (1998).	
	DW	Horton John et al. "Tamoxifen In Advanced Prostate Cancer" An ECOG Pilot Study", The Prostate 12: 173-177 (1988).	
	DX	Hayes "A Randomized Comparison Of Tamoxifen, Trioxifene And A New Estrogen Antogonist (LY117018) In Rats And Mice" In Life Sciences, 1980, vol. 26, pp. 1453-1458.	
	DY	Jordan Craig V. "Antiestrogenic Action of Raloxifene and Tamoxifen: Today and Tomorrow" Journal of National Cancer Institute, Vol. 90, No. 13, July 1, 1998	
	DZ	Warri Anni. M. et al "Apoptosis in Toremifene Induced Growth Inhibition of Human Breast Cancer Cells in Vivo and In Vitro" Journal of National Cancer Institute, Vol. 85, No. 17, September 1, 1993	
	EA	Mobbs, B.G. et al "Concentration and Cellular Distribution of Androgen Receptor in Human Prostatic Neoplasia: Can Estrogen Treatment Increase Androgen Receptor Content?" J. Steroid Biochem. Vol. 19, No. 3 pp. 1279-1290, 1983.	

		 ** * *****
Examiner	Date	
Signature	 Considered	

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INF	ORMA	TION	I DISCLOSURE	Filing Date	December 30, 2003		
STATEMENT BY APPLICANT			BY APPLICANT	First Named Inventor	STEINER, Mitchell S.		
ļ				Group Art Unit	1615		
(use as many sheets as necessary)			eets as necessary)	Examiner Name	Not yet known		
Sheet	9	of	9	Attorney Docket Number	P-2769-US9		

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	EB	Krieg, Michael et al "Androgens and Estrogens: Their Interaction with Stroma and Epithelium of Human Benign Prostatic Hyperplasia and Normal Prostate" J. Steroid Biochem. Vol. 19, No. 1 pp. 155-161, 1983	
	EC	Hard, Gordon C. et al. "Major Difference in the Hepatocarcinogenicity and DNA Adduct Forming Ability between Toremifene and Tamoxifen in Female Crl. CD(BR) Rats" Cancer Research 53, 4534-4541, October 1, 1993	
	ED	Boyle Peter et al "Epidemiology of Prostate Cancer Chemoprevention" Eur Urol 1999: 35:370-376	
		Bostwick, David G. et al "Reversibility of Prostatic Intraepithelial Neoplasia: Implications for Chemoprovention" Eur. Urol 1999: 35:492-495	
	EF	Bostwick David "Prospective Origins of Prostate Carcinoma" American Cancer Society 1996	
	EG	The Lancet "The Challenge of Breast Cancer" Vol. 342, September 18, 1993	
	EH	Zaridze, David G. et al "International Trends in Prostatic Cancer" Int. J. Cancer: 33, 223-230 (1984)	
	E!	Nevaluinen MT et al "Hormone regulation of human prostate in organ culture" Cancer Res. 1993 Nov 1:53 (21):5199-207	
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